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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,086	05/30/2006	Dominique Jean-Pierre Mabire	PRD-2121 USPCT	1676
27777	7590	08/11/2009		
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER JABLE, CECILIA M	
			ART UNIT	PAPER NUMBER
			1624	
			MAIL DATE	DELIVERY MODE
			08/11/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/596,086

**Applicant(s)**

MABIRE ET AL.

**Examiner**

Cecilia M. Jaisle

**Art Unit**

1624

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 April 2009.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-4, 6, 12, 13, 15, 16, 27, 28 and 31-33 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☒ Claim(s) 4, 16, 31 and 32 is/are allowed.  
6) ☒ Claim(s) 2, 3, 6, 12, 13, 15, 27, 28 and 33 is/are rejected.  
7) ☒ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## DETAILED OFFICE ACTION

### *Rejections Under 35 USC 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, 6, 12, 13, 15 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which the specification does not describe in such a way as to reasonably convey to one skilled in the relevant art that the inventors, when the application was filed, had possession of the claimed invention. This is a new matter rejection.

There is no support in the application as filed for the added proviso in currently amended claim 2 "that when n is 0, X is N, R2 is hydrogen, R3 is **Z**, Z is the heterocyclic ring system (c-2) or (c-4) wherein said heterocyclic ring system Z is attached **to the rest of the molecule** with a nitrogen atom, and R10 is hydrogen; then R4 is other than **hydrogen**, C1-6alkyl or pyridinyl." Applicants supposedly point to support for the added proviso in original claim 1. However, the claim 1 proviso states:

"when n is 0, X is N, R2 is hydrogen, R3 is a group of formula (b-1), Z is the heterocyclic ring system (c-2) or (c-4) wherein said heterocyclic ring system Z is attached to the rest of the molecule with a nitrogen atom, and R10 is hydrogen; then R4 is other than hydrogen, C1-6alkyl or pyridinyl."

The phrases in bold in currently amended claim 2 differ from the original claim 1 proviso. Applicants do not provide reasons for the differences, or how the specification as filed supports the identified proviso in currently amended claim 2.

Introduction of claim changes which involve claim narrowing by introducing elements or limitations not supported by the as-filed disclosure is a violation of 35 USC 112, first paragraph, written description requirement. See *Fujikawa v. Wattanasin*, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus; it does not "reasonably lead" one skilled in the art to any particular species or sub-genus).

The application as filed does not disclose the proposed new proviso in *ipsis verbis*. *Ipsis verbis* disclosure is not necessary to satisfy section 112 written description requirement. Instead, the disclosure need only reasonably convey to persons skilled in the art that applicant had possession of the subject matter in question. *In re Edwards*, 196 USPQ 465, 467 (CCPA 1978). In other words, the question is whether the present "application provides adequate direction which reasonably [would lead] persons skilled in the art" to the sub-genus of the proposed claim. As was remarked by the Court of Customs and Patent Appeals more than forty years ago and remains true today:

It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail . . . to be confronted simply by a large number of unmarked trees. [Applicants] are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.

*In re Ruschig*, 154 USPQ 118, 122 (CCPA 1967).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 6, 12, 13, 15, 27, 28 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**Claim 2:**

- It is not understood what is meant in the proviso by "Z is attached with a nitrogen atom." Note that the definition of R3 shows that Z is a divalent moiety and there is no definition of what is attached to the Z extra valence. Further, it is not understood what is intended by "with a nitrogen atom." It is not possible for Z to be attached by nitrogen, because the intended ring nitrogen is undefined. The ring nitrogen atom in Z has a hydrogen substituent and can support no further substituents. It is not possible for an extra nitrogen to be interposed between the Z moiety and R3, because such a structure is not provided for by formula (I) and such a structure would have unsatisfied nitrogen valences.
- The R6 definition "arylcarbonylpiperidinylC1-6alkyl or arylC1-6alkyl(C1-6alkyl)-aminoC1-6alkyl" is not understandable. The carbonyl-to-piperidinyl attachment is undefined. It is unclear how the 3 C1-6 alkyl moieties are arranged in the last recited R6 definition. Are they in a single line or are 2 attached to the amino group?
- The Z moiety (c-2) is undefined.
- The R10 definition "C1-6alkyloxyC1-6alkylamino" is not understandable. It is unclear how the two C1-6 alkyl moieties are arranged. Are they in a single line or are the oxy moiety and the C1-moiety 6 attached to the amino group?

- The new aryl definition confuses the previous use of the term aryl. "Aryl" is not used alone previously in the claim. Are the arylC1-6alkyl moiety of R4 and the arylcarbo-nylpiperidinyC1-6alkyl or arylC1-6alkyl(C1-6alkyl)-aminoC1-6alkyl moieties of R6 to be understood to have the additional substituents on their included aryl moieties?

**Claims 12, 27, 28, 33:**

- It is not understood what is intended by a "chemotherapeutic agent." The specification recites cisplatin and bleomycin as chemotherapeutic agents (§ 0015). The specification also recites examples of chemotherapeutic agents that may be used in conjunction with radiosensitizers include, but are not limited to: adriamycin, camptothecin, carboplatin, cisplatin, daunorubicin, docetaxel, doxorubicin, interferon (alpha, beta, gamma), interleukin 2, irinotecan, paclitaxel and topotecan (§ 0156).

***Allowed Claims***

Claims 4, 16, 31 and 32 are allowed. An examiner's statement of reasons for allowance can be found in the Office Action of May 15, 2008.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cecilia M. Jaisle whose telephone number is 571-272-9931. The examiner can normally be reached on Monday through Friday; 8:30 am through 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the

examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. If you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cecilia M. Jaisle/  
Patent Examiner, AU 1624

**/James O. Wilson/  
Supervisory Patent Examiner, AU 1624**